K070155

510(k) SUMMARY

OSSEO SCIENTIFIC, LLC
INTEGRITY LOW SPEED HANDPIECE & ATTACHMENT

1. Submitter Name, Address, Phone/Fax

Registration No. 3005405362

JAN 25 2007

Osseo Scientific, LLC
3138 Veeder Ave.
Toms River, NJ 08753
USA
Telephone # 201-490-5421
Facsimile # 201-490-5423

2. Contact Person-Owner

Michael Feldman
Telephone # 732-597-5971

3. Date summary prepared: October-28-2006

4. Device Name:

Trade Name: INTEGRITY Low Speed Dental Air Handpiece and Accessories.
Model No's INT-E, INT-D, INT-SNC.

Common Name: Handpiece Low Speed Dental.

Classification Name: Dental Handpiece and Accessories.
(21CFR 872.4200)

Product Code: 76 EFB ("Handpiece, Air-Powered, Dental").

Device Class: Class I

5. Indications for Use:

The INTEGRITY Air Powered Low Speed Handpieces are intended for removing curious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations and polishing teeth for use by a trained professional in general dentistry.

6. Predicate Device Name:

For Model INT-E: A-dec/W&H Synea & TreND Low Speed (K944713 & K993526) and Dabi Atlante Low Speed (K926154).
For Model INT-SNC: A-dec/W&H Synea & TreND (K993526), Dabi Atlante (K926155) and MK-dent Straight Handpiece (K051872)

For Model INT-D: Promident Low Speed (K781545)

7. Description of Device:

The Integrity Low Speed Handpiece is a 5-vane motor, ranging in speed up to 20,000 RPM, and is compatible to all standard 2, 3 or 4 hole fixed air connection. It accepts all brands of ISO E-Type or U-Type attachments. The Motors and Straight Nose Cone are used for general dentistry procedures.

8. Substantially Equivalence- Safety and Effectiveness:

The INTEGRITY Low Speed handpieces share virtually all specifications and design characteristics of the predicate devices and are Identical or similar based on comparisons of formulations and intended uses as shown below. The handpieces are constructed of materials of identical specification as the predicate device. Air Connection, and interface with other dental attachments were Identical. Air Pressure and, speed Results were similar. It is therefore Substantially Equivalent to one or more dental handpieces currently marketed in the USA.

The Handpieces conform to applicable ISO standards. The ability to repeatedly adequately sterilize the device is being confirmed by validation protocol, and will be available for inspection before the device is marketed.

- Intended use;.....Identical
- Indications for use;.....Identical
- Target population;.....Identical
- Anatomical sites;.....Identical
- Where used (hospital, home, ambulance, etc);..... Identical
- Energy used and/or delivered;..... Identical
- Human factors;..... Identical
- Design;..... Similar
- Performance;..... Identical
- Standards met..... Identical
- Materials..... Identical

- Biocompatibility..... Not Applicable
- Compatibility with the environment and other devices..... Identical
- Sterility..... Identical
- Mechanical safety.....Identical
- Electrical safety.....Not applicable
- Chemical safety.....Not applicable
- Thermal safety..... Not applicable
- Radiation safety.....Not applicable

8. Conclusion: Based on information in the notification Osseo Scientific, LLC believes that INTEGRITY Air Powered Low Speed Handpieces are substantially equivalent to the claimed predicate, i.e.,

For Model INT-E: A-dec/W&H Synea & TreND Low Speed (K944713 & K993526) and Dabi Atlante Low Speed (K926154).
For Model INT-SNC: A-dec/W&H Synea & TreND (K993526), Dabi Atlante (K926155) and MK-dent Straight Handpiece (K051872)
For Model INT-D: Promident Low Speed (K781545)

Voluntary Standard Compliance:

ISO Standard 7785-2: Low Speed Dental Handpiece.

ISO Standard 1797: Shank Dimensions.

ISO Standard 9168: Hose Connectors.

ISO Standard 3964: Coupling Dimensions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2007

Osseo Scientific, LLC
C/O Mr. Neil E. Devine
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K070155
Trade/Device Name: Integrity Low Speed Air Dental Handpiece and Attachment
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: January 16, 2007
Received: January 17, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070153

Device Name: Integrity Low Speed Air Dental Handpiece and Attachment.

Models: Motor INT-E, Motor INT-D and Attachment INT-SNC

Indications for Use:

The INTEGRITY Air Powered Low Speed Handpieces are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations and polishing teeth for use by a trained professional in general dentistry.

Prescription Use		Over-The-Counter Use
__x_____	AND/OR	_____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K070153